

## **REMARKS**

Claims 1 and 5 are currently under examination. The currently outstanding office action sets forth rejections based on 35 USC §102(b), and §103. Applicants have amended claim 1 to specify that the probiotic bacteria adhere on the pericarp of olives in amounts of  $1 \times 10^6$  per gram of olive. Applicants have also added a new claim 8 directed to the table olives of claim 1 characterized in that they contain probiotic lactobacilli and/or bifidobacteria adhering on the pericarp in amounts sufficient to increase at least one logarithmic cycle the intestinal population of the probiotic bacteria population upon ingestion. Support for the amendment of claim 1 can be on page 6, line 8 through page 7, line 3 of the specification. Support for new claim 8 can be found in Example 3, Experiment 1, of the specification. In view of the foregoing amendments and the following remarks, it is respectfully submitted that all of the pending claims are allowable, and reconsideration is respectfully requested.

Applicants thank Examiner Macauley for the courtesy extended to Applicant's representative during the interview of November 6, 2009. During the interview, the §102 and §103 art based rejections were discussed.

### **I.     **The Claims Are Not Anticipated, or Rendered Obvious, by the Cited Prior Art****

Claims 1 and 5 are rejected under 35 U.S.C. §102(b) as anticipated by or, in the alternative, under 35 U.S.C. §103(a) as obvious over Jimenez et al. (WO 02/056695A1: "Jimenez"), Ojeda (WO 00/60948A1; "Ojeda"), or Suskovic et al. (Food Technol. Biotechnol., 1997, 35:107-112; "Suskovic").

According to the Examiner, both Jimenez and Ojeda both teach vegetables, such as olives, that have been fermented with *Lactobacillus*. The references teach that the *Lactobacillus* secretes bacteriocin, and thus would provide probiotic benefits. Further, Suskovic is said by the Examiner, to teach that it is known in the art to ferment vegetables, such as olives, with *Lactobacillus* and that *Lactobacillus* has probiotic properties. For reasons detailed below, Jimenez, Ojeda and Suskovic fail to anticipate, or render obvious, the presently claimed invention, when considered either alone or in combination.

In order for a reference to anticipate a claim, each and every element of the claim must be disclosed in that one reference. *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565 (Fed. Cir. 1985). "Anticipation under Section 102 can be found only if a

reference shows exactly what is claimed. . .” *Structural Rubber Prod. Co. v. Park Rubber Co.*, 749 F.2d 707 (Fed. Cir. 1984).

Further, regarding obviousness, a claim is invalid if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. 35 U.S.C. § 103(a). The consistent criterion of determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in light of the prior art. *Brown & Williamson Tobacco Corp. v. Philip Morris Inc.*, 229 F.3d 1120, 1124 (Fed. Cir. 2000).

Applicants have amended claim 1 to specify that the probiotic bacteria is *Lactobacillus paracasei* and adheres on the pericarp of olives ***in amounts of  $1 \times 10^6$  per gram*** of olive. Applicants have also added a new claim 8 directed to the table olives of claim 1 characterized in that they contain probiotic *Lactobacillus paracasei* adhering on the pericarp in amounts sufficient to increase at least one logarithmic cycle the intestinal population of the probiotic population upon ingestion.

The present invention is based on the surprising result that probiotic bacteria adhere to the pericarp of the olives in levels sufficient to exert a beneficial action on the gastro-intestinal tract of a subject. As set forth in Example 1 of the specification, when olives are stored in brine containing lactobacilli and/or bifidobacteria, including *Lactobacillus paracasei*, for three months, ***removed from the brine*** and tested for adherence of bacteria to the pericarp, it is observed that the pericarp allows for tight anchorage of the bacteria. Additionally, as set forth in Example 3 of the specification, a sufficient number of probiotic bacteria, *i.e.*, *Lactobacillus paracasei*, adhere to the surface of the olives of the invention so that following ingestion the population of bacteria in human subjects increases about two logarithmic cycles. Following suspension of ingestion of the olives, the levels of the probiotic bacteria decrease, demonstrating a correlation between the ingestion of the olives of the invention and the increased presence of probiotic bacteria in the gastrointestinal tract.

In contrast, both Ojeda and Jimenez fail to teach the adherence of probiotic bacteria to the pericarp of olives in levels sufficient to exert a beneficial action on the gastrointestinal tract of a subject. Both cited references merely disclose inoculating the

brine in which vegetable products, including olives, are fermented with ***the specific bacteria Lactobacillus plantarum*** for the purpose of improving the taste, aroma and quality of the fermented product. It is believed that such a result is due to the production of a bacteriocin called plantaricin S ***by this specific bacteria*** which reduces spoilage and deterioration of the fermented product, i.e., the bacteriocin effects are against the bacteria contaminating the fermentation process. The bacteriocin production that Ojeda and Jimenez teach is not related to probiotic properties. Ojeda and Jimenez fail to teach the “*in vivo*” use of *L. plantarum* having the probiotic property of adhering on the surface of olives. That Ojeda and Jimenez are concerned with only the benefit derived from bacteriocin production, and not the probiotic properties of the bacteria, is supported by the fact that both references only teach the use of the bacteria *Lactobacillus plantarum* and not the use of other types of bacteria, including the *Lactobacillus paracasei* recited in the claims, having probiotic properties.

Thus, both Ojeda and Jimenez fail to disclose, or even suggest, that after removal from the inoculated brine, ***probiotic bacteria, such as Lactobacillus paracasei, adhere to the pericarp of the olives***, much less that they adhere in amounts of  $1 \times 10^6$  or higher per gram of olive, as required by the presently pending claims. Thus, Ojeda and Jimenez fail to disclose each and every element of the claim as required by the law. Furthermore, with regard to Suskovic, Applicants maintain that Suskovic merely discloses studies relating to the testing of the resistance properties of *Lactobacillus plantarum* L4 to antibiotics, lysozyme, and salts of bile only, Suskovic fails to disclose that such bacteria adhere tightly to the pericarp of olives. Furthermore, Suskovic fails to teach the “*in vivo*” use of *L. plantarum* having the probiotic property of adhering on the surface of olives.

Thus, given the differences between the disclosures of Jimenez, Ojeda and Suskovic and the disclosure of the present invention, the claims as amended, simply cannot be anticipated, or rendered obvious, by Jimenez, Ojeda and Suskovic. Applicants maintain that the prior art simply does not disclose, nor would it have suggested to one of ordinary skill in the art, that olives stored in brine containing *Lactobacillus paracasei* would have said bacteria adhered to their pericarp in levels greater than  $1 \times 10^6$ . Thus, Applicants respectfully request withdrawal of the rejections under §102 (b) or §103.

**CONCLUSION**

It is respectfully submitted that the present application is now in condition for allowance, early notice of which is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

If any fees are required in connection with the filing of this amendment, the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,

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